REMARKS

In the outstanding Office Action, Claims 1, 3-7, 16-18, 25-27, 29, and 30 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Number 5,766,225 to Kramm in view of U.S. Patent Number 4,708,142 to DeCote, Jr. Claims 1, 2, 7-9, 11-13, 14-18, and 22-30 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Number 6,278,894 to Salo et al. in view of DeCote, Jr. Claims 3, 6, 10, and 19-21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Salo et al. in view of DeCote, Jr. and further in view of U.S. Patent Number 5,476,485 to Weinberg et al. Reconsideration is respectfully requested in light of the following remarks.

Claims 1, 18, and 27 are directed to a method and corresponding system that provides biventricular pacing to capture both the right and left ventricles. According to the method, biventricular pacing is achieved by delivering a **single** pacing pulse in a cross-chamber configuration between an electrode associated with the left ventricle and an electrode in the right ventricle, which results in the synchronous capture of both ventricles. In other words, using an electrode configuration that includes an electrode in the right ventricle and an electrode on the left side of the heart, the claimed invention achieves simultaneous, biventricular capture with a single pacing pulse.

The Examiner rejected Applicant's claims based on the Kramm patent, which incorporates by reference U.S. Patent Number 4,932,407 to Williams, in view of the DeCote, Jr. patent. The Kramm patent briefly mentions pacing, but does not disclose any specifics about how it paces the heart. Kramm simply teaches that "If the brady escape interval has timed out, a pace pulse is delivered as illustrated at 68." (Col. 5, lines 63-64). Nowhere does Kramm discuss or even mention biventricular pacing. Kramm only discloses the use of pacing to differentiate between sustained and non-sustained arrhythmias. Obviously this has nothing to do with biventricular pacing.

Kramm incorporates by reference the Williams patent because Williams discloses a lead that may be used with Kramm's defibrillator (Col. 3, lines 7-9). According to the Examiner, Williams discloses a system that performs synchronous biventricular stimulation. However, nowhere does Williams teach or in any way suggest

providing a single, cross-chamber pacing pulse between an electrode in the right ventricle and an electrode on the left side of the heart to achieve simultaneous, biventricular pacing. Williams merely teaches conventional pacing with bipolar electrodes in each chamber; thus, for biventricular pacing, Williams teaches delivering a first pacing pulse to a pair of electrodes in the right ventricle, and then delivering a second pacing pulse to a separate pair of electrodes on the left side of the heart.

Williams does teach applying defibrillation shocks between an electrode in the right ventricle and an electrode on the left side of the heart. But in regards to pacing, Williams specifically uses two different sets of electrodes, one for pacing the right ventricle, and another for pacing the left ventricle. Thus, there is no teaching or suggestion in Williams of using the defibrillation electrode configuration for pacing, since Williams specifically teaches using other electrode configurations to achieve bi-ventricular pacing.

The Examiner cites DeCote, Jr. for teaching appropriate pacing pulse energy levels. Even assuming that there is some suggestion to combine these references, none of these references teach or in any way suggest delivering a single pacing pulse in a cross chamber configuration to achieve biventricular pacing with a single pacing pulse. Williams specifically teaches using **separate pairs** of electrodes to pace different chambers of the heart. Moreover, none of the references provide any suggestion or motivation to modify Williams to deliver a single cross-chamber pacing pulse to achieve biventricular pacing. Thus, even if DeCote, Jr. were combined with Kramm and Williams, one still does not arrive at Applicant's claimed invention. Williams teaches pacing the right ventricle with two electrodes 20 and 22, and pacing the right atrium with two separate electrodes 50 and 52. Williams further teaches electrodes 62 and 64 placed in the coronary sinus, but does not mention using any of those electrodes in a **cross-chamber configuration** for biventricular **pacing**.

Thus, in order to arrive at Applicant's claimed invention, one must modify the teaching of Williams by using one of Williams' shocking vectors, adjusting the stimulation energy to a level for pacing, and then delivering a single pacing pulse along the defibrillation vector to achieve simultaneous biventricular capture. It is respectfully submitted that the Examiner is using impermissible hindsight reconstruction to arrive at

this rejection. Williams himself teaches pacing, but never mentions using the defibrillation vectors for pacing. Williams explicitly provides one set of electrode configurations for pacing, and a different set of electrode configurations for providing defibrillation shocks. Therefore, Williams describes a system that paces and shocks, but never himself considered using a cross-chamber configuration to perform pacing. The Examiner is therefore attempting to modify Williams in a manner that Williams never considered, even though he did consider how to achieve multi-chamber pacing. Clearly the Examiner is using hindsight reconstruction to modify the teachings of Williams in a manner that was non-obvious to even Williams himself.

As set out above, none of the references teach or in any way suggest using a single pacing pulse applied in a cross-chamber configuration to achieve multi-chamber pacing. Moreover, modifying the teachings of Williams as proposed by the Examiner is improper hindsight reconstruction.

The Salo et al. patent is directed to a system that measures impedance by delivering AC signals between right and left ventricular leads. The Examiner characterizes Salo et al. as a "multi-site stimulator", and that "[a] single bi-ventricular pacing pulse is used to synchronously capture in both ventricles (abstract; col. 2 @49-56)". It is respectfully submitted that the Examiner has misread Salo et al. The abstract is clearly describing a system for determining **impedance values**, which Salo et al. define as using an AC signal "whose amplitude is below that which is required to evoke capture" (col. 4, lines 24-25). At column 2, lines 49-62, Salo et al. mention using a coronary vein lead for pacing, and that the coronary vein lead may be "combined with a right ventricular or right atrial lead to span the left ventricular blood volume. A high frequency current source and sensing amplifier may be connected to electrodes available on these leads in a number of ways to **measure electrical impedance**. In each of these configurations, the sensing electrodes span some region of the left ventricle and would, therefore, be sensitive to left ventricular volume and wall motion." (col. 2, lines 55-62).

Thus, when Salo et al. refer to combining the coronary vein lead with a right-sided lead to "**span the left ventricular blood volume**", it is for the purpose of delivering sub-threshold signals to measure electrical impedances, not for the purpose of delivering pacing pulses. The purpose of pacing pulses is to stimulate heart tissue, and is not concerned with spanning ventricular blood volume. Impedance signals, on the other hand, are concerned with the ventricular blood volume, because that is what they are intended to measure. Clearly, Salo et al. are describing delivering sub-threshold **impedance** signals between electrodes in the right ventricle and electrodes on the coronary vein lead to determine ventricular blood volume, and not cross-chamber pacing pulses to achieve bi-ventricular capture. Salo et al. therefore do not teach or in any way suggest a system that delivers **pacing pulses** between an electrode on the right side of the heart and an electrode on the left side of the heart.

Moreover, modifying Salo et al. to change it from delivering sub-threshold signals to delivering pacing pulses as suggested by the Examiner would defeat the main purpose of Salo et al., namely to determine impedance values **without** stimulating the heart tissue. One cannot simply modify a reference without taking that reference's teaching into account; there must be some suggestion or motivation from the reference that it be modified as the Examiner is suggesting. Clearly in this case one skilled in the art would not be motivated to change an impedance measuring circuit into a pacing circuit. The two are quite different, have completely different objectives, and modifying the circuit as the Examiner proposes would defeat the main purpose of Salo et al., namely to measure impedance without capturing the heart.

Claims 3, 6, 10, and 19-21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Salo et al. in view of DeCote, Jr. and further in view of U.S. Patent Number 5,476,485 to Weinberg et al. As described above, Salo et al. and DeCote, Jr. fail to teach or suggest a method of biventricular pacing that delivers a **single** pacing pulse in a cross-chamber configuration between the right and left ventricles to synchronously capture both ventricles. Likewise, Weinberg et al. fail to teach or suggest delivering a single pacing pulse between an electrode in the right ventricle and an electrode associated with the left ventricle. Therefore, the prior art, whether taken alone or in combination, fails to teach applicant's claimed invention.

CONCLUSION

In light of the above remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

4/15/04
Date

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